



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

5W

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,951	07/25/2003	Peter M. Bonutti	781-A03-006-2	3215

33771 7590 11/30/2004

PAUL D. BIANCO: FLEIT, KAIN, GIBBONS,
GUTMAN, BONGINI, & BIANCO P.L.
601 BRICKELL KEY DRIVE, SUITE 404
MIAMI, FL 33131

EXAMINER

DOSTER GREENE, DINNATIA JO

ART UNIT PAPER NUMBER

3743

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/626,951

Applicant(s)

BONUTTI ET AL.

Examiner

Dinnatia Doster-Greene

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Detail Action.

Art Unit: 3743

DETAILED ACTION

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Longfellow (U.S. Patent No. 2,191,283) in view of Burkhead et al. (U.S. Patent No. 5,385,536). Longfellow discloses a first drive assembly (35, 34, 36, 40) and a second drive assembly (37, 51, 55, 56, 57). The first drive assembly moves upper and lower sections of the orthosis relative to the base section about an axis which extends beneath an axilla of the patient's body. Shown in Fig. 1 in Longfellow, the upper arm section connects with an upper portion of the arm of the patient. The second drive assembly rotates the lower arm section and the lower portion of the arm of the patient about a second axis which extends through opposite ends of the upper portion of the arm of the patient and through a shoulder of the patient (Longfellow, column 2, line 30 – column 3, line 22).

Art Unit: 3743

Thus, Longfellow discloses the claimed invention with the exception of a specific recitation of connecting the lower arm section with a lower portion of the arm of the patient. However, Burkhead, which also relates to a shoulder and arm orthopedic brace, discloses that it is known in the art to utilize a forearm strap 104 to secure a patient's arm to the forearm contour pad 98. Thus, it would have been obvious to one skilled in the art at the time of the invention to modify the forearm cradle 53 of Longfellow with the forearm strap 104 of Burkhead for the purpose of securing the patient's arm to the forearm cradle.

As to claims 2-8, since the device in Longfellow is operated manually, Longfellow also teaches the steps of interrupting operation of the second drive assembly; operating and interrupting the second drive assembly; the patient interrupting operation of the second drive assembly based on the patient's comfort level; maintaining the lower arm section rotational position after interruption of operation of the second drive assembly; permitting rotation only in one direction; operating the second drive assembly for a second time to further rotate the lower arm section and the lower portion of the arm about the second axis; and performing the steps in a single treatment session.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 3743

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claim 1 is rejected under the judicially created doctrine of double patenting over claim 30 of U. S. Patent No. 6,599,263 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows:

A method of effecting movement between bones in a patient's body, said method comprising the steps of connecting a base section of an orthosis with a trunk of the patient's body, operating a first drive assembly to move upper and lower arm sections of the orthosis relative to the base section about an axis which extends beneath an axilla of the patient's body, connecting the upper arm section with an upper portion of the arm of the patient, connecting the lower arm section with a lower portion of the arm of the patient, and operating a second drive assembly to rotate the lower arm section and the lower portion of the arm of the patient about a second axis which extends through opposite ends of the upper portion of the arm of the patient and through a shoulder of the patient.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during

Art Unit: 3743

prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Brudny (U.S. Patent No. 4,417,569).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dinnatia Doster-Greene whose telephone number is 571-272-7143. The examiner can normally be reached on 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-7143.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Henry Bennett
Supervisory Patent Examiner
Group 3700

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: P. Bonutti

Attorney Docket No.: 781-A03-006-2

Application No.: To Be Assigned
(Continuation of App. No.: 09/556,458)
Filed: Herewith

Group Art Unit:
Examiner:

For: SHOULDER ORTHOSIS

**INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 C.F.R. § 1.56**

Commissioner for Patents
Alexandria, VA 22313

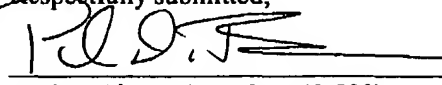
Sir:

In accordance with the duty of disclosure provisions of C.F.R. § 1.56, there is hereby provided certain information, which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

A revised Form PTO/SB/08 listing all patents, publications, applications, or other information submitted for consideration is enclosed. Copies of the listed documents from prior Application No.: 09/579,038, filed May 26, 2000, of which this application claims priority under 35 U.S.C. § 120, are not being submitted pursuant to 37 C.F.R. § 1.98(d).

No admission is made that the information cited in this Statement is, or is considered to be prior art, material to patentability nor a representation that a search has been made.

This Information Disclosure Statement is filed under 37 C.F.R. § 1.97(b) before the latter of three months after the U.S. patent application filing date or the first Office Action on the merits. Accordingly, no fee or certification is required.

Dated: July 25, 2003 Respectfully submitted,


Paul D. Bianco (Reg. No. 43,500)
Attorney for Applicant
Fleit, Kain, Gibbons, Gutman & Bongini, P.L.
601 Brickell Key Drive
Suite 404
Miami, Florida 33131
305-931-9620 (telephone)